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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DR

March 25, 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of List B Phase IV package for Irgasan
(DP Barcode D159725; EFGWB# 91-0294 and 91-0300,
Chemical# 054901, Case# 2340)

TO: Amy Rispin, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (H7507C)

THRU: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

FROM: Elizabeth A. Resek, Chemist
Environmental Chemistry Review Section #1
Environmental Fate and Ground Water Branch (H7507C)

Attached is the Phase IV package for List B chemical Irgasan

Use Patterns

The LUIS report for irgasan dated 2/16/91 indicates that the use patterns are:

Aquatic Non-Food Residential
Indoor Non-Food
Indoor Residential

Environmental Fate Data Requirements

The following data are required:

- (161-1) Hydrolysis
- (161-2) Photodegradation in Water

A summary of the status of environmental fate data requirements is shown in the attached table.



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PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR Irgasan (Case # 2340)

Chemical Code : 91-0300, 91-0294
 Pesticide Type : _____

Reviewer: E. Resek
 Date: 3/25/91

Uses (Luis 2/6/91): Aquatic Non-Food, Indoor Non-Food, Indoor Residential

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
CHEMICAL/PHYSICAL DATA:				
160-5. Chemical Identity	None	YES	YES	YES
DEGRADATION-LAB:				
161-1. Hydrolysis	None	YES	YES	YES
<u>Photodegradation:</u>				
161-2. In Water	None	YES	YES	NA
161-3. On Soil	None	NA	NA	NA
161-4. In Air	None	NA	NA	NA
METABOLISM-LAB:				
162-1. Aerobic Soil	None	NA	NA	NA
162-2. Anaerobic Soil	None	NA	NA	NA
162-3. Anaerob. Aquat.	None	NA	NA	NA
162-4. Aerobic Aquatic	None	NA	NA	NA
MOBILITY STUDIES:				
163-1. Leaching and Ads. Des.	None	NA	NA	NA
163-2. Volatil.(Lab)	None	NA	NA	NA
163-3. Volatil.(Field)	None	NA	NA	NA

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE (continued)

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Identification	Additional Data/Info Required?
<u>DISSIPATION-FIELD:</u>				
164-1. Terrestr.(Soil)	None			NA
164-2. Aquat.(Sediment)	None			NA
164-3. Forestry	None			NA
164-4. Combin./Tank Mix	None			NA
164-5. Long Term Terr.	None			NA
164-5. Long Term Aqua.	None			NA
<u>ACCUMULATION STUDIES:</u>				
165-1. Conf. Rot. Crops	None			NA
165-2. Field Rot. Crops	None			NA
165-3. Irrigated Crops	None			NA
165-4. Fish (Lab)	None			NA
165-5. Aqua. Non-target Organ.(Field)	None			NA
<u>SPRAY DRIFT:</u>				
201-1. Droplet Spect.	None			NA
202-1. Field Spray Drift Evaluation	None			NA
<u>GROUNDWATER MONITORING:</u>				
166-1. Small Prospect.	None			NA
166-2. Small Retrop.	None			NA
166-3. Large Retrop.	None			NA
<u>SURFACE WATER:</u>				
167-1. Field Runoff	None			NA
167-2. Surface Water Monitoring	None			NA

(M)

KEY:

- 1) Addendum(EFGWB#/Date) = placed in the second column to indicate that a review (having the indicated EFGWB# and date) of the addendum identified by MRID# in the first column/same row is in the file.
- 2) DER(EFGWB#/Date) = placed in the second column to indicate that a data evaluation record for the study identified by MRID# in the first column/same row is in the file attached to a review with the indicated EFGWB# and date.
- 3) DNS/Salv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).
- 4) DNS/Salv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (Supp.).
- 5) DNS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (NSupp.).
- 6) DNS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).
- 7) DNPS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).
- 8) DNPS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).
- 9) DNPS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

10) DNPS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).

11) Dropped Uses(codes) = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that all uses for which the data requirement is applicable will be dropped. Verify through the LUIS report that the uses have been dropped.

12) MRID#/MRID#A = placed in the first column to indicate that the study and addendum (A) whose MRID#s immediately proceed and succeed the "/" respectively, are coupled. If a MRID# was not assigned to the addendum, substitute the date of submission for the MRID# followed by an "A" to indicate that it's an addendum. If neither a MRID# or submission date is available, but the addendum was submitted as part of the Phase III response, substitute "Phase IIIA" for "MRID#A".

13) NA = placed in last (4th) column to indicate that the data requirement is not applicable to the uses listed in the LUIS report.

14) No = placed in the final (4th) column to indicate that no additional information or data is needed to completely satisfy an applicable data requirement. Identify in a footnote any studies that individually only partially satisfied the data requirement, but combined completely satisfies the data requirement. If the data requirement is not applicable to any of the uses listed in the LUIS report, use the "NA" designation defined above instead of "No".

15) No Information = placed in the second column to indicate that no DER or summary is available for the study identified by MRID# in the first column/same row, and that the registrant has not indicated in their Phase III response that they will submit another study or will drop uses to make the data requirement not applicable.

16) None = placed in the first column to indicate that the registrant did not list any studies or addendums in their Phase II and/or III responses for the given data requirement. In addition, EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirement.

17) Not Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row will not satisfy or partially satisfy the data requirement and appears not to be salvageable to do so. Therefore, the study should not be reviewed.

18) Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row may possibly satisfy or partially satisfy the data requirement, or could possibly be salvageable to do so. Therefore, the study should be reviewed.

19) Reserved = placed in the final (4th) column to indicate that the data requirement is being held

in reserve. Indicate in a footnote what information is needed to decide whether or not to impose the data requirement.

20) SIRReview = placed in the final (4th) column to indicate that one or more studies is currently in review.

21) Study Withdrawn = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that another study will be submitted.

22) Summary(MRID#) = placed in the second column to indicate that a DER is not available for the study identified by MRID# in the first column/same row, but that a study summary with the indicated MRID# was submitted as part of the Phase III response. If a summary is submitted for a study which also has a DER, identify the DER in the second column instead of the summary. (Note that the MRID# of the summary is not the same as the MRID# of the study it summarizes).

23) SWBSubmitted = placed in the final (4th) column to indicate that one or more studies will be submitted by the registrant as indicated in their Phase III response.

24) Waived = placed in the final (4th) column to indicate that the data requirement has been waived. Identify the reason for the waiver and the EFGWB#/date of EFGWB's waiver recommendation in a footnote.

25) Yes = placed in the final (4th) column to indicate that additional information and/or data are needed to satisfy the data requirement. Specify in a footnote what additional information and/or data are needed.

FOOTNOTES:

- a. The chemical identity data are incomplete for Irgasan.
- | | |
|--------------------|----------------|
| Vapor Pressure | Not Determined |
| Kow | Not Determined |
| pKa | Not Determined |
| Solubility (Water) | Not Determined |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

March 26, 1991

MEMORANDUM

SUBJECT: Transmittal of EFED List B Review for Irgasan (Case # 2340; Chemical # 054901)

FROM: Amy Rispin, Chief *Amy Rispin*
Science Analysis and Coordinatin Staff
Environmental Fate and Effects Division

TO: Jay Ellenberger, Chief
Generic Chemical Support Branch
Special Review and Reregistration Division

Attached please find the following documents for the completed EFED review of Irgasan.

1. EFGWB review.
2. EEB review.
3. SACS Reregistration Summary Report

If you have any questions concerning this case, please contact Betsy Grim at 557-7634.

cc (with SACS Reregistration Summary Report attached)

Anne Barton
Paul Schuda
Urban
List B File
List B Cover Memo File

Hank Jacoby
Elizabeth Leovey

Jim Akerman

Doug

SACS REREGISTRATION SUMMARY REPORT
for Phase IV

FROM: Betsy Grim, SACS, EFED
THRU: Amy Rispin, Chief SACS
TO: Ruby Whitters, SRRD

Date: March 26, 1991

Amy Rispin
Active Ingredient:

List B

Irgasan Chemical 054901

1. Background/history

Even though the LUIS report lists Aquatic Non-Food Residential as a use, it is only used as such in swimming pool water systems, and hence, the abbreviated data requirements.

2. Use Pattern (Sites) and Application Rate.

The LUIS report dated 2/16/91 indicates that the use patterns are: Aquatic Non-Food Residential, Indoor Non-Food and Indoor Residential.

3. Registration Information

A. Kind of pesticide.

Antimicrobial agent to impart bacteriostatic activity to articles (principally textile fabrics.) Disinfectant, fungicide repellent/feeding depressant,tuberculocide.

B. Target. Microrganisms

Sites listed in the LUIS report include bathroom premises/hard surfaces, carpets human body/clothing while being worn, laundry, leather, paper, plastic, rubber, swimming pool water systems, textiles, toilet bowls, and upholstery.

C. Method of application.

Method of application includes: by hand, washing machines, brush, cloth, sponge, additive, rinse, spray, industrial preservative treatment, and shampoo.

D. Formulation Issues and Structure:

According to the LUIS report Irgasan is supplied as a dust, wettable powder, emulsifiable concentrate, soluble concentrate liquid and liquid-ready to use.

5-Chloro-2(2,4-dichlorophenoxy)phenol

4. EEB Disciplinary Summary To highlight special issues

The registrant has asked for waivers for the 71-1(a) Acute Avian Oral Test, the 71-2(b) Acute Avian Dietary Test, and the 72-2(a) Acute Aquatic Invertebrate Test based on the low volume and indoor use of this product. These waivers can be granted for the end use product, but additional ecological effects testing is required using the manufacturing use product as the test substance. Therefore, the following data are required to support the registration of Irgasan (for Indoor Use and Aquatic Use for swimming pool water systems only), and its manufacturing use product is a solid formulation:

- 71-1(a) Avian Acute Oral (bobwhite quail)
- 71-2(a) Avian Dietary (bobwhite quail)
- 72-1(c) Freshwater Fish (rainbow trout)
- 72-2(a) Freshwater Invertebrate (Daphnia)

5. EFGWB Disciplinary Summary To highlight special issues

The only EFGWB data requirements based on the limited uses, i.e., Indoor and Aquatic Non-Food Residential (swimming pool water systems) are:

- 161-1 Hydrolysis
- 161-2 Photodegradation in Water

Chemical identity (160-5) must also be submitted.

6. Integrating Paragraph to highlight special issues

Both branches reviewed Irgasan for the Aquatic Non-Food Residential use as limited to swimming pool water systems. If there are other out-door uses the data requirements may change.

7. Ecotoxicity studies to be flagged for early review for tier or other decisions

None at this time.

8. Any data waivers, special considerations, or special study needs? (special information needed for data waivers)

See EEB Summary for data waiver information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 15, 1991

NOV
OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of List B Phase IV package for Irgasan
(DP Barcode D159725, EFGWB# 91-0294 and 91-0300,
Chemical# 054901, Case# 2340)

TO: Amy Rispin, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (H7507C)

THRU: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

FROM: Elizabeth A. Resek, Chemist
Environmental Chemistry Review Section #1
Environmental Fate and Ground Water Branch (H7507C)

Attached is the Phase IV package for List B chemical Irgasan

Use Patterns

The LUIS report for irgasan dated 12/3/90 indicates that the use patterns are:

Terrestrial Food Crop
Terrestrial Non-Food Crop
Outdoor Residential

Environmental Fate Data Requirements

The following data are required:

- (161-1) Hydrolysis
- (161-2) Photodegradation in Water
- (161-3) Photodegradation on Soil
- (162-1) Aerobic Soil Metabolism
- (162-2) Anaerobic Soil Metabolism
- (162-3) Anaerobic Aquatic Metabolism
- (163-1) Leaching and Adsorption/Desorption
- (163-2) Lab Volatility
- (164-1) Terrestrial Field Dissipation
- (165-1) Confined Rotational Crop
- (165-4) Bioaccumulation in Fish

The following data requirements are reserved:

- (161-4) Photodegradation in Air
- (163-3) Field Volatility
- (164-5) Long Term Terrestrial Field Dissipation
- (165-2) Field Accumulation in Rotational Crop

A summary of the status of environmental fate data requirements is shown in the attached table.

According to the LUIS report it appears that the application rate is 27.588 lb a.i./A.

The Phase IV package included only information on the physical data of irgasan and the label. No environmental fate summaries or studies were included. Attached is a summary of the physical data.

The following is the physical and chemical information for irgasan:

C ₆ H ₄ (C ₆ H ₅)OH	
Molecular Weight	170.2
Boiling Point	547 F
Solubility of Water	0.08g/100g
Vapor Pressure (@ 140 C)	7 mm Hg
Specific Gravity	1.2
Dissociation Constant	
p-Nitrophenol	7.14 (25 C)
Benzoic Acid	4.14 (20 C)
p-Chloroaniline	4.05 (20 C)

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR Irgasan (Case # 2340)

Chemical Code : 91-0300, 91-0294
 Pesticide Type : _____

Reviewer: E. Resek
 Date : 1/15/90

Uses (Luis 12/3/90): Terrestrial Food, Terrestrial Non-Food, Outdoor Residential

Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
CHEMICAL/PHYSICAL DATA:			
160-5. Chemical Identity 41667001 Summary(91-0300/1-15-91) YES ^a			
00101697			
00164227			
00164228			
DEGRADATION-LAB:			
161-1. Hydrolysis	None	YES	
<u>Photodegradation:</u>			
161-2. In Water	None	YES	
161-3. On Soil	None	YES	
161-4. In Air	None	RESERVED ^b	
METABOLISM-LAB:			
162-1. Aerobic Soil	None	YES	
162-2. Anaerobic Soil	None	YES	
162-3. Anaerob. Aquat.	None	YES	
162-4. Aerobic Aquatic	None	NA	
MOBILITY STUDIES:			
163-1. Leaching and Ads. Des.	None	YES	
163-2. Volatil. (Lab)	None	YES	
163-3. Volatil. (Field)	None	RESERVED ^c	

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE (continued)

Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
<u>DISSIPATION-FIELD:</u>			
164-1. Terrestr. (Soil)	None	YES	
164-2. Aquat. (Sediment)	None	NA	
164-3. Forestry	None	NA	
164-4. Combin./Tank Mix	None	NA	
164-5. Long Term Terr.	None	RESERVED ^d	
164-5. Long Term Aqua.	None	NA	
<u>ACCUMULATION STUDIES:</u>			
165-1. Conf. Rot. Crops	None	YES	
165-2. Field Rot. Crops	None	RESERVED ^e	
165-3. Irrigated Crops	None	NA	
165-4. Fish (Lab)	None	YES	
165-5. Aqua. Non-target Organ. (Field)	None	NA	
<u>SPRAY DRIFT:</u>			
201-1. Droplet Spect.	None	YES	
202-1. Field Spray Drift Evaluation	None	YES	
<u>GROUNDWATER MONITORING:</u>			
166-1. Small Prospect.	None	NA	
166-2. Small Retrop.	None	NA	
166-3. Large Retrop.	None	NA	
<u>SURFACE WATER:</u>			
167-1. Field Runoff	None	NA	
167-2. Surface Water Monitoring	None	NA	

KEY:

- 1) Addendum(EFGWB#/Date) = placed in the second column to indicate that a review (having the indicated EFGWB# and date) of the addendum identified by MRID# in the first column/same row is in the file.
- 2) DER(EFGWB#/Date) = Placed in the second column to indicate that a data evaluation record for the study identified by MRID# in the first column/same row is in the file attached to a review with the indicated EFGWB# and date.
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- 9) DNPS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

- 10) DNPS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.)
- 11) Dropped Uses(codes) = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that all uses for which the data requirement is applicable will be dropped. Verify through the LUIS report that the uses have been dropped.
- 12) MRID#/MRID#A = placed in the first column to indicate that the study and addendum (A) whose MRID#s immediately precede and succeed the "/" respectively, are coupled. If a MRID# was not assigned to the addendum, substitute the date of submission for the MRID# followed by an "A" to indicate that its an addendum. If neither a MRID# or submission date is available, but the addendum was submitted as part of the Phase III response, substitute "Phase IIIA" for "MRID#A".
- 13) NA = placed in last (4th) column to indicate that the data requirement is not applicable to the uses listed in the LUIS report.
- 14) No = placed in the final (4th) column to indicate that no additional information or data is needed to completely satisfy an applicable data requirement. Identify in a footnote any studies that individually only partially satisfied the data requirement, but combined completely satisfies the data requirement. If the data requirement is not applicable to any of the uses listed in the LUIS report, use the "NA" designation defined above instead of "No".
- 15) No Information = placed in the second column to indicate that no DER or summary is available for the study identified by MRID# in the first column/same row, and that the registrant has not indicated in their Phase III response that they will submit another study or will drop uses to make the data requirement not applicable.
- 16) None = placed in the first column to indicate that the registrant did not list any studies or addendums in their Phase II and/or III responses for the given data requirement. In addition, EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirement.
- 17) Not Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row will not satisfy or partially satisfy the data requirement and appears not to be salvageable to do so. Therefore, the study should not be reviewed.
- 18) Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row may possibly satisfy or partially satisfy the data requirement, or could possibly be salvageable to do so. Therefore, the study should be reviewed.

19) Reserved = placed in the final (4th) column to indicate that the data requirement is being held in reserve. Indicate in a footnote what information is needed to decide whether or not to impose the data requirement.

20) SIReview = placed in the final (4th) column to indicate that one or more studies is currently in review.

21) Study Withdrawn = placed in the second column to indicate that there are no DERS or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that another study will be submitted.

22) Summary(MRID#) = placed in the second column to indicate that a DER is not available for the study identified by MRID# in the first column/same row, but that a study summary with the indicated MRID# was submitted as part of the Phase III response. If a summary is submitted for a study which also has a DER, identify the DER in the second column instead of the summary. (Note that the MRID# of the summary is not the same as the MRID# of the study it summarizes).

23) SWBSubmitted = placed in the final (4th) column to indicate that one or more studies will be submitted by the registrant as indicated in their Phase III response.

24) Waived = placed in the final (4th) column to indicate that the data requirement has been waived. Identify the reason for the waiver and the EFGWB#/date of EFGNB's waiver recommendation in a footnote.

25) Yes = placed in the final (4th) column to indicate that additional information and/or data are needed to satisfy the data requirement. Specify in a footnote what additional information and/or data are needed.

FOOTNOTES:

a. The chemical identity data are incomplete for Irgasan. The following product chemistry data are required to support an environmental fate profile for Irgasan.

Vapor Pressure Row	7 mm Hg (140 °C) Not Determined
pKa	
p-Nitrophenol	7.14 (25 °C)
Benzoic Acid	4.14 (20 °C)
p-Chloroaniline	4.05 (20 °C)
Solubility (Water)	0.08g/100g

b. Photodegradation studies in air are reserved pending review of both product chemistry data and an acceptable laboratory soil volatility study.

c. Field volatility studies are reserved pending review of an acceptable laboratory volatility study.

d. Long-term terrestrial field dissipation studies are reserved pending review of acceptable field dissipation studies.

e. Field rotational crop studies are reserved pending review of an acceptable confined rotational crop study.